Exhibit #1

510(k) SUMMARY

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K101504.

1. Submitter's Identification:

OCT 2 9 2010

Essential Dental Systems
89 Leuning Street
South Hackensack, NJ 07606

Date Summary Prepared: May 28, 2010
Date Summary Revised: October 15, 2010

Contact: Mr. Jeffrey Wan
Contact Phone #: 201-487-9090 ext. 118
Contact Fax #: 201-487-5120

2. Name of the Device:

Trade name: Ti-Core® Flow+
Common name: dental resin cement
Classification name: dental cement (21 CFR 872.3275, Product Code EMA)

3. Predicate Device Information:

1. Fluorocore 2+, K#083326, Dentsply International, York, PA

2. ParaCem Universal DC, K#053040, Coltene/Whaledent AG, New York, NY

3. Ti-Core Natural, K#922251, Essential Dental Systems, South Hackensack, NJ

4. Device Description:

Ti-Core® Flow+ is a dual-cure resin cement that can be used as a luting agent and core material. It is packaged in the familiar double-barrel syringe configuration used by countless other dental materials. The steps required to properly express the cement are: remove cap, attach mixer, attach dispensing tip, press plunger. After use, the mixer/dispensing tip should be discarded and the cap replaced.

The contents of the kit are

2 – Dual chambered syringes each containing 9 gm resin cement
20 – Mixers
10 – Thin dispensing tips
10 – Thick dispensing tips

5. Intended Use:

Ti-Core® Flow+ is indicated for vital or non-vital tooth core build-up (replacement of existing restorations and/or lost tooth structure), as a base prior to fabricating an indirect restoration, and as a post cement. Ti-Core® Flow+ is also indicated for cementing of endodontic posts, crowns, bridges, inlays, onlays, and for core build-ups.

6. Comparison to Predicate Devices:

The subject device is similar to Fluorocore 2+ and ParaCem Universal in that they are dual-cure resin cement that can be used as a luting agent and core material. These materials are packaged in the familiar double-barrel syringe configuration used by countless other dental materials. The directions for use for these materials are nearly identical. On a high level, the formulation of these products are the same. They are comprised of two pastes each containing methacrylate monomers with glass and/or quartz fillers. One paste contains photoinitiators and cure accelerators while the other contains self-cure initiators.

Because detailed formulations for these two predicate devices do not appear in the public domain, we have cited an additional predicate device for which we do have complete formulation data for: Ti-Core Natural. The subject device contains the same components of Ti-Core Natural with the addition of the popular photoinitiators camphorquinone and ethyl 4 dimethylamino benzoate and the methacrylate resin dimethylaminoethyl methacrylate.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:

Biocompatibility literature supplied with this 510(k) submission along with Material Safety Data Sheets, has shown that the materials in Ti-Core® Flow+ do not raise any new safety/biocompatibility concerns.

Non-clinical performance testing for Ti-Core® Flow+ and Fluorocore 2+ was conducted according to ISO standard 4049. This includes evaluation of film thickness, working and setting time, sensitivity to ambient light, depth of cure, flexural strength, water solubility and sorption, and radiopacity. Results of the testing conclude that Ti-Core® Flow+ meets or exceeds the ISO specification except for radiopacity, which is not claimed by the proposed device.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

Ti-Core® Flow+ has the same intended use and similar technological characteristics as the predicate devices. Moreover, the literature supplied in this submission demonstrates that any differences in their material formulations do not raise any new questions as to safety or effectiveness. Thus, Ti-Core® Flow+ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jeffery Wan
Research & Development Manager
Essential Dental Systems, Incorporated
89 Leuning Street, Suite 8
South Hackenack, New Jersey 07606

Re: K101504
Trade/Device Name: Ti-Core® Flow^{+}
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: October 15, 2010
Received: October 19, 2010

OCT 29 2010

Dear Mr. Wan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): K101504

OCT 29 2010

Device Name: Ti-Core® Flow+

Indications for Use:

Ti-Core® Flow+ is indicated for vital or non-vital tooth core build-up (replacement of existing restorations and/or lost tooth structure), as a base prior to fabricating an indirect restoration, and as a post cement. Ti-Core® Flow+ is also indicated for cementing of endodontic posts, crowns, bridges, inlays, onlays, and for core build-ups.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over the Counter Use ____
(Per 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101504